Non-Confidential Summary of Safety and Effectiveness

16-Feb-09 K090421

Inspired Technologies, Inc.
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Official Contact: Rick Confer – Director RA/QA

Proprietary or Trade Name: Model 350G Gas Conserver

Usual Name: Conserver, oxygen

Classification Name: Noncontinuous ventilator (IPPB)
NFB - 868.5905

Predicate Devices: Sunrise PD 1000 – K020329
Inspired Technologies VIAspire Model 300P LOX portable – K072011
Essex – Hi Pressure OCD - K024023

Device Description:
The Inspired Technologies Model 350G Gas Conserver is designed to extend the use time of oxygen cylinders. It contains an integral pressure regulator with CGA 870 style yoke. The pressure regulator reduces the cylinder pressure to 19 - 25 psig. While the device is normally operated in the conserving mode, there is a continuous flow over-ride switch that allows 2 LPM of oxygen to bypass all valves for delivery to the patient. This continuous flow mode is typically used in the event of low or no battery power. In the conserving mode, the 350G Gas Conserver delivers oxygen to the patient by sensing inhalation via a pressure switch and opening one, two or both control valves for a specified period of time as determined by the microprocessor control algorithm. In the conserving mode, the device uses SmartDose™ technology to accomplish the oxygen savings. SmartDose™ senses the start of inhalation and releases a short "pulsed" dose at the very beginning of the inhalation cycle. The 350G Gas Conserver intended to be used by trained clinicians in the hospital, clinical or home care environments.

Indications for Use:
The Inspired Technologies 350G Gas Conserver is intended as a delivery device for medial-grade oxygen from high-pressure oxygen cylinders. This is an ambulatory device, which allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder. The 350G Gas Conserver is intended to be used in the hospital, healthcare facilities, or home care environments.

Patient Population:
Patients on oxygen

Environment of Use:
Hospital, healthcare facilities, or home care environments.

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Features	Model 350G Gas Conserver
Software driven	Yes
Components	Integral high pressure regulator Dosing device and algorithm Valves
Pressure reduction from high pressure cylinders	Yes
Dosing algorithm	16.0 cc/lpm x setting value (i.e. 16x 1=16, 16 x 2 =32 etc) at 1.0, 1.5, 2.0, 2.5, 3.0, 4.0, 5.0, and 6.0 Lpm flow settings Sport mode 1 is setting value + 16 cc Sport Mode 2 is setting value +32 cc/lpm
Back up mode flow rate	Continuous flow in back-up mode of 2 Lpm
Powered and duration	4 "AA" batteries
Status indicators	Battery Status Patient setting-valve activation
Breath sensing	Pressure switch range (vacuum) 0.03 to -0.200 cm H_2O
Dosing	Up to 35 BPM at maximum settings (5)
Alarms	Visual battery low alert No audible alarms
Data Storage	SD card used for storage of data

To demonstrate safety and efficacy we performed the following tests according to the following standards:

FCC CFR 47 Parts 15B and 18
Industry Canada
BS EN 55011:2007
IEC 60601-1
Bench and performance testing for:
Low battery voltage tests
Battery Life
Battery reverse polarity
Pressure regulator verification
Storage at high and low temperatures
Operation at high and low temperatures
Cleaning verification
IPX1 –Drip proof verification

Differences Between Other Legally Marketed Predicate Devices:

The proposed device is viewed as substantially equivalent to the predicate devices, Sunrise - PD 1000 – K020329, Inspired Technologies – VIAspire LOX Portable - K072011, and Essex – Hi Pressure OCD - K024023

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2009

Inspired Technologies, Incorporated
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

Re: K090421
Trade/Device Name: 350G Gas Conserver
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: NFB
Dated: May 15, 2009
Received: May 18, 2009

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., MA
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K090421 (To be assigned)

Device Name: 350G Gas Conserver

Indications for Use:

The Inspired Technologies 350G Gas Conserver is intended as a delivery device for medial-grade oxygen from high-pressure oxygen cylinders. This is an ambulatory device, which allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder.

The 350G Gas Conserver is intended to be used in the hospital, healthcare facilities, or home care environments.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090421